

FEB 22 2005

Page 1 of 4
November 15, 2004

SMDA 510(k) SUMMARY

K042274

Electrosurgical unit PSD-60, ENDOPLASMA, ACCESSORIES

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

A. GENERAL INFORMATION

1. Applicant

Name & Address:

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Registration Number:

2. Initial Importer

Name & Address:

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2429304

Registration Number:

3. Submission Correspondence

Name

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Address

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B. DEVICE IDENTIFICATION

1. Common/Usual Name

Electrosurgical Unit, Argon Plasma Coagulation Unit and Accessories

2. Device Name

Electrosurgical Unit PSD-60, ENDOPLASMA , ACCESSORIES

3. Classification Name

	Classification panel	Product code	Class
878.4400	Electrosurgical cutting and coagulation device and accessories	GEI	II
876.4300	Endoscopic Electrosurgical Unit and accessories	KNS	II

C. IDENTIFICATION OF LEGALLY MARKETING DEVICES WHICH WE CLAIM SUBSTANTIAL EQUIVALENCE

The following listed devices are seem to be as predicate devices in consideration of its characteristic and the following table shows regulatory history.

Model	510(k)#	Manufacturer	Class	P-Code
ERBE VIO ESU, Model VIO300D	#k023886	ERBE Elektromedizin GmbH	II	GEI
UES-20 Electrosurgical System and associated Accessories	#k970184	OLYMPUS	II	GEI
XUES-41 Endoscopic Electrosurgical unit	#k030194	OLYMPUS	II	KNS
ERBE VIO APC, Model APC-2	#k024047	ERBE Elektromedizin GmbH	II	GEI

D. DEVICE DESCRIPTION

1. Summary

1) PSD-60 technology

The PSD-60 is an Electrosurgery unit and is used in conjunction with a OLYMPUS ENDOPLASMA. or can be used alone. The PSD-60 has a 7-segment LCD (Liquid Crystal Display) that provides the user with an on-screen setting and operational information.

The unit has various cutting and coagulation modes with defined effect levels to provide the physician flexibility in applications (i.e. Its ability is to generate the HF current.). The system has automatic start and stop features. When activated, the device has an alarm as well as a visual error system (i.e. malfunctions or user errors are detected with medical personnel being alerted visually and/or by sound with, in some cases, no energy being delivered.).

Upon activation, energy delivered from the PSD-60 to the tissue is displayed in watts on the 7-segment display. Also, the unit can be used in association with an OLYMPUS compatible ENDOPLASMA Argon plasma coagulator. The unit is non-sterile and is reusable.

2)ENDOPLASMA technology

The OLYMPUS ENDOPLASMA is an Argon plasma coagulation system and is used in conjunction with an OLYMPUS PSD-60.

The PSD-60 provides high frequency (HF) voltage to electrically charge Argon gas from the ENDOPLASMA to form plasma in the gas stream when in close proximity to tissue. Current density concentrates at the tissue surface from ENDOPLASMA (probe) causes coagulation. The ENDOPLASMA with the PSD-60 has a 7-segment LCD (Liquid Crystal Display) that provides the user with an on-screen setting operational information.

Software in the PSD-60 controls the microprocessor chip in an ENDOPLASMA. The PSD-60/ENDOPLASMA are programmable and have error monitoring features. There is a communications bus cable for the PSD-60 to communicate with an ENDOPLASMA. A pressure reducer with sensor is provided to regulate the Argon gas going into the ENDOPLASMA. The ENDOPLASMA and its accessory are supplied non-sterile and are reusable. Cleaning/ disinfection, and sterilization (as applicable) are provided in the respective user manual .

The ENDOPLASMA membrane filter is also a part of the system. The filter is disposable single-use. The filter is connected between the ENDOPLASMA (at the Argon gas port) and connector hose. The filter creates a barrier to protect the ENDOPLASMA from potential contamination. Filters are supplied sterile by means of ethylene oxide and are disposable (single use). They are sterilized by the manufacturer and the sterilization cycle has been validated.

3) Accessories

① Footswitch

A footswitch is provided to the physician as a means to activate a mode of the PSD-60 by depressing a foot pedal. A footswitch has two pedals. One is for cutting, and the other is for coagulating.

② P-cord

P-cord is provided to connect the single use of patient plate to the PSD-60.

③ APC-cable

APC-cable is provided to transmit HF energy and argon gas to ENDOPLASMA probe.

④ APC-probe

APC-probe is provided to mix HF energy and argon gas to form ENDOPLASMA and provide plasma energy to the surface of tissue.

⑤ Irrigation adapter

Irrigation adapter is provided to clean the ENDOPLASMA probe.

⑥ Pressure reducer

Pressure reducer is provided to reduce pressure provided from the gas cylinder.

⑦ S-cord

S-cord is provided to connect the metal part of Endoscope to the PSD-60.

2. Design

This device has been designed to be complying with the following voluntary standards.

- IEC 60601-1 • IEC60601-1-1 • IEC 60601-1-4 • UL2601-1
- IEC 60601-2-2 • IEC 60601-1-2 (EMC) • EN60529 • AAMI/ANSI HF-18
- IEC 60601-2-18

3. Materials

There aren't any patient contacting materials in PSD-60 and ENDOPLASMA. Some ancillary equipment have patient contact materials, however, there are no new patient contacting materials in those devices.

4. Intended Use of the device

The PSD-60 has been designed to be used with OLYMPUS endoscope (fiberscope, video scope and rigid scope) compatible with electrosurgical accessories and other ancillary equipment for general, laparoscopic and endoscopic electrosurgery (cutting, coagulation, including soft tissue coagulation).

The argon plasma coagulation unit has been designed to be used with the electrosurgical unit, OLYMPUS PSD-60 for argon plasma coagulation (APC) of living tissues in treatment using OLYMPUS endoscope compatible with electrosurgery, argon plasma coagulation accessories and other ancillary equipment for endoscopic electrosurgery (coagulation).

E. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Theory of the operation of OLYMPUS PSD-60 and ENDOPLASMA are that the electrical energy generation in PSD-60 is supplied to human tissue via endoscopic therapy devices in order to cut and coagulate the human tissue. The system can cut and coagulate the human tissue by high frequency energy. This system is equivalent to the predicate devices, ERBE VIO300D (K023886), OLYMPUS UES-20 (K970184), ERBE VIO APC2 (K024047) and ERBE APC300 (K963189).

F. CONCLUSION

When compared to the predicate devices, PSD-60 and ENDOPLASMA do not incorporate any significant changes in the intended use, method of operation, materials, or design that could affect safety and effectiveness. Therefore, clinical data is not necessary for evaluation of safety and efficacy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 22 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus Shirakawa Company, Ltd.
c/o Mr. Daniel W. Lehtonen
Intertek Testing Service
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K042274

Trade/Device Name: Electrosurgical Unit PSD-60, ENDOPLASMA, Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 4, 2005
Received: February 7, 2005

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Miriam C Provost
for

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K042274

Device Name:

Electrosurgical Unit PSD-60, ENDOPLASMA, Accessories

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter-Use
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K042274

Page 1 of 1

4
(5)